

CERTIFICATE OF ANALYSIS

 Date
 04-Feb-2020

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Kreon 10000 20caps

 Material
1123941

 Batch
58641

 Prod. date
 11.2019

 Expiry date
 10.2021

Characteristic	Unit	Result	Specification
Appearance bi-coloured hard gelatin capsules size 2 with brown opaque cap and colourless transparent body filled with brownish pellets		complies	see characteristic
Ident.: Amylase (enzyme activity test)		positive ident.	Positive identification
Ident.: Lipase (enzyme activity test)		positive ident.	Positive identification
Ident.: Proteases (enzyme activity test)		positive ident.	Positive identification
Uniformity of dosage units (Mass varia.) L1 = 15.0% , L2 = 25.0% acceptance value = k*s and M=X(mean)		complies	complies to Ph.Eur.
Assay: Amylase	PhEurU/cps	13334	>= 8000
Assay: Lipase	PhEurU/cps	11256	11000 .. 13000
Assay: Proteases	PhEurU/cps	772	>= 600
Water content of pellets	%	3.1	<= 4.0
Residual solvents: Isopropyl alcohol	%	0.2	<= 0.5
Residual solvents: Acetone	%	0.4	<= 0.5
Dissolution test	%	106	see footnote *)
Disintegration time (Water)	min.	4	<= 15
Total aerobic microbial count (TAMC)	cfu/g	40	<= 10000
Total combined yeast/moulds count (TYMC)	cfu/g	10	<= 100
Bile-tolerant gram-negative bacteria	/g	< 10	<= 100
Salmonella		absent / 10 g	absent / 10 g
Escherichia coli		absent / 1 g	absent / 1 g
Staphylococcus aureus		absent / 1 g	absent / 1 g

*) requirement for Dissolution test:

The higher value (after 20 min or 30 min) should be not less than 80% (Q) of the labelled lipase activity.

Date of manufacture (DD.MM.YYYY): 20.11.2019

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10.2021**Analytical test methods listed in specification document (allocation number in SOLID see below):**

<u>Test</u>	<u>Test method</u>
Appearance	visual examination
Identification	Ph.Eur. / SOLID 0000082709
Uniformity of dosage units (mass variation)	Ph.Eur. 2.9.40
Assay	SOLID 0000082709
Water content of pellets	SOLID 0000082711
Residual solvents	P0000101
Dissolution test	SOLID 0000088309
Disintegration of capsule	Ph.Eur. 2.9.1
Total aerobic microbial count TAMC	Ph.Eur. 2.6.12
Total combined yeast/moulds count TYMC	Ph.Eur. 2.6.12
Bile-tolerant gram-negative bacteria	Ph.Eur. 2.6.13
Salmonella	Ph.Eur. 2.6.13
Escherichia coli	Ph.Eur. 2.6.13
Staphylococcus aureus	Ph.Eur. 2.6.13

The regulatory compliance regards the following countries:

Russian Fed. RegN°
P No.015581/01SpecN°
SOLID 1000627671 Version 2.0

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10.2021**CERTIFICATE OF CONFORMITY**

Package: 20 capsules in a white HDPE bottle with a tamper-evident PP screw cap.
A label is applied on the bottle.
1 sealed and labled bottle together with the Instruction for Medical Use in a carton.

Labelling: In accordance with the Normative Document.

Storage: Do not store above 25 °C. Store in a tightly closed package.

Shelf Life: 2 years
Shelf life after first opening of a bottle is 3 months.

Manufacturer of Active Ingedient (API) used in manufacture of this batch:

Abbott Laboratories GmbH

Werk Neustadt

Justus-von-Liebig-Str. 33

D-31535 Neustadt a. Rbge.

Germany

Manufacturer's License Number: DE_NI_02_MIA_2019_0011/41401/H-144

Certificate of GMP Compliance: DE_NI_02_GMP_2019_0013

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

The batch is in compliance with Normative Document P N015581/01-130417 var. #1-2.

This certificate was generated by a validated system and signed electronically.

04.02.2020 / 15:52:24 CET e-sign: David Schwarzer, Qualified Person,
Certificate checked and approved